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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/014,196	02/04/93	HUSTON J	CRF-008DV(20

HM11/0907

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY & PO
ONE FINANCIAL CENTER
BOSTON MA 02111

EXAMINER	
ULM, J	

ART UNIT	PAPER NUMBER
1646	34

DATE MAILED: 09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office action restarted.

UNITED STATE)EPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ILM,J	
ART UNIT	PAPER NUMBER
1646	34

DATE MAILED: 08/09/01

HM12/0809

PATENT ADMINISTRATOR
TESTA, HURWITZ & THIBEAULT
53 STATE STREET
BOSTON MA 02109

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/014,096	Huston et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 27, 2000* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *47-53, 56-61, and 63-68* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *47-49, 51-53, 56-61, and 63-68* is/are rejected.

7) ☒ Claim(s) *50* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1) Claims 47 to 53, 56 to 61 and 63 to 68 are pending in the instant application.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 stand rejected under 35 U.S.C. 102(e) as being anticipated by the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131) for those reasons of record in section 5 of Paper Number 31.

Applicant has traversed this rejection on the premise that it is in conflict with the decision in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981). In that decision, the court held that:

> "New matter can add material limitations that transform unpatentable invention, when viewed as whole against prior art, into patentable one; continuation-in-part application, unlike continuation application, does not necessarily insure that all critical aspects of later disclosure were present in parent; thus, in such situation, only application disclosing patentable invention before new matter's addition, which disclosure is carried over into patent, can be relied upon to give reference disclosure benefit of its filing date for purpose of supporting Sections 102(e)/103 rejection."

The instant claims have been rejected because they encompass the two fusion proteins which were described on page 15 of the initial Cousens et al application Serial Number 06/717,209, filed 28 March of 1985, as "GAP_P M BCA5 KRSTS PYK PYK_t" and "GAP_P M BCA5 $KR(ST)_2S$ SOD

GAP_t". These two fusion proteins were also described in TABLE 1 of the Cousens et al. patent which issued from the subsequently filed application Serial Number 06/845,737, filed 28 March of 1986, which was a continuation in part of the '209 application. Applicant's arguments in traversal of this rejection are not persuasive because those arguments are based upon the two false premises that the two fusion proteins upon which the rejection is based were not patentable at the time that the '209 application was filed and that they do not meet all of the limitations of the instant claims.

First, Applicant has failed to identify the basis of unpatentability of the "GAP_P M BCA5 KRSTS PYK PYK_t" and "GAP_P M BCA5 $KR(ST)_2S$ SOD GAP_t" proteins. The DNA constructs encoding those two fusion proteins are encompassed by the subsequently issued claims of the Cousens et al. patent. Therefore, the DNAs encoding those two proteins must be free of the art since a generic claim is unpatentable over any art which anticipates or renders obvious any single embodiment encompassed by that generic claim (M.P.E.P. 2131.02). Because the DNA encoding the fusion protein and the protein encoded thereby reflect the same inventive concept then one would have to reasonably conclude that these two fusion protein were free of the prior art, absent evidence to the contrary. Of course, if Applicant is aware of any prior art which rendered these two proteins unpatentable as of the filing date of the '209 application then Applicant is encouraged to make that art of record. Of course, since these two proteins are encompassed by the instant claims that art will have to be applied accordingly.

Further, Applicant has failed to identify a basis of unpatentability of the "GAP_P M BCA5 KRSTS PYK PYK_t" and "GAP_P M BCA5 $KR(ST)_2S$ SOD GAP_t" proteins based upon a lack of enablement, written description or utility. Given the description of these two proteins provided by the '209 application, one of ordinary skill could have readily made and used those two proteins by following the routine practices in the art at the time that the initial Cousens et al. application was filed. Therefore, had claims to these two fusion proteins and the DNAs encoding them been presented in either of the Cousens et al. applications, those claims would have been allowed since they were enabled, useful and free of the prior art.

Applicant's argument that the initial Cousens et al. et al. application required the addition of new matter to render those two proteins patentable is without merit. The new matter added in the subsequently filed Cousens et al. application was needed to support **broader** claims than could be supported by the initial Cousens et al. application, and it was those broader claims which issued in the Cousens et al. patent. Had Cousens et al. accepted the issuance of claims to the two fusion proteins and the DNAs encoding them in the initial application then they would have had to deal with obviousness-type-double patenting issues against the generic claims in the subsequent application. That additional matter was not needed to support the patentability of claims limited to the two fusion proteins upon which the instant rejection is based and the DNAs encoding them, but that matter was essential to support the broader generic claims which subsequently issued in the Cousens et al. patent.

Second, Applicant urges that the "GAP_P M BCA5 KRSTS PYK PYK_t" and "GAP_P M BCA5 $KR(ST)_2S$ SOD GAP_t" proteins of Cousens et al. do not meet all of the limitations of the instant claims because the amino acid sequence of the hinge region in each of these proteins is not cysteine free. Applicant is encouraged to identify a cysteine residue (C) in each of the amino acid sequences KSTS and KRSTSTS, which inherently constitute the hinge regions of the two fusion proteins of Cousens et al. These sequences are clearly free of cysteine residues.

5) Claims 60 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131). as applied to claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 above, and further in view of the Cohen et al. patent (4,743,679) for those reasons of record in section 6 of Paper Number 31.

6) Claim 50 stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. There was no motivation to incorporate a proline residue into a flexible linker like that of Cousens et al. since it was well known in the art at that time that the presence of a proline residue in such a linker would have created a "rigid kink" in that linker, as disclosed on page 131 of the Lehninger reference.

7) Applicant's arguments filed 29 May of 2001 have been fully considered but they are not persuasive for those reasons given above.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800